UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/518,408	03/03/2000	Kristin M. Lundy	PC10487A	7372

23913 7590 04/10/2002

PFIZER INC
150 EAST 42ND STREET
5TH FLOOR - STOP 49
NEW YORK, NY 10017-5612

EXAMINER	
JONES, DWAYNE C	
ART UNIT	**PAPER NUMBER**
1614	7

DATE MAILED: 04/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/518,408	Applicant(s) LUNDY, KRISTIN M.	
	Examiner Dwayne C Jones	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *15 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of Claims

1. Claims 1-21 are pending.

2. Claims 1-21 are rejected.

Response to Arguments

3. Applicant's arguments with respect to claims 1-21 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the acetylcholinesterase inhibitors as depicted by the compounds of Formula I, does not reasonably provide enablement for other types of acetylcholinesterase inhibitors. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. All questions of enablement are evaluated against the claimed subject matter. The question asked by one skilled in the art is whether everything within the scope of the claim is enabled. The instant claims cover all compounds having the pharmaceutical property of being an acetylcholinesterase inhibitor. Accordingly, the instant specification only provides

guidance and support for acetylcholinesterase inhibitors as embraced by the compounds of Formula I. The Federal Circuit has repeatedly held that "the specification must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation'." In re Wright, 999 f.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). One does not look to the claims but to the specification to find out how to practice the invention. W.L. Gore & Assoc., Inc. v. Garlock, Inc., 721 F.2d 1540, 1558, 220 USPQ 303, 316-7 (Fed. Cir. 1983); In re Johnson, 558 F.2d 1008, 1017, 194 USPQ 187, 195 (CCPA 1977).

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 17-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claims 17-21 recite the limitation "Formula I" in line 1. There is insufficient antecedent basis for this limitation in the claim. Each of these claims fails to provide a structure to coincide with the compound of Formula I. It is suggested that the compound and the embodiments of Formula I be incorporated into an independent claim to obviate this confusion.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

10. Claim 1 is rejected under 35 U.S.C. 102(a) as being clearly by anticipated by Giovannini et al. Giovannini et al. teach of the administration of acetylcholinesterase inhibitors, such as metrifonate, for the treatment of Alzheimer's disease, (see abstract).

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-3 rejected under 35 U.S.C. 102(b) as being clearly anticipated by Bryson et al. Bryson et al. teach of the administration of an acetylcholinesterase inhibitor, namely donepezil, for the treatment of Alzheimer's disease, (see abstract). Bryson et al. also teach that the administration of an acetylcholinesterase inhibitor improves cognitive function.

13. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Cheng et al. Cheng et al. teach of the administration of an acetylcholinesterase inhibitor, namely huperzine A, for the treatment of Alzheimer's disease, (see abstract). Cheng et al. also teach that with the administration of an acetylcholinesterase inhibitor memory deficits were reversed. Cheng et al. also disclose that an acetylcholinesterase inhibitor is a therapy for cognitive impairment.

14. Claim 7 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Leonard et al. Leonard et al. teach of the administration of an acetylcholinesterase inhibitor, namely neostigmine, for the modulation of REM sleep states, (see abstract).

15. Claims 4, 9, 10, 13, 16-18 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by O'Malley et al. of U.S. Patent No. 5,494,908. O'Malley et al. teach of the benzisoxazole compounds and that these compounds are anticholinesterase inhibitors. O'Malley et al. also teach that these compounds are effective in the treatment of Alzheimer's disease, (see abstract and columns 19-26). O'Malley et al. also teach of pharmaceutical preparations of these compounds, (see column 25).

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

18. Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Malley et al. of U.S. Patent No. 5,494,908. O'Malley et al. teach of the benzisoxazole compounds and that these compounds are anticholinesterase inhibitors. O'Malley et al. also teach that these compounds are effective in the treatment of Alzheimer's disease, (see abstract and columns 19-26). O'Malley et al. also teach of pharmaceutical preparations of these compounds, (see column 25). Although the prior art reference of O'Malley et al. do not specifically teach of treating of the cognitive disorders recited by the instant claims, O'Malley et al. do state the benzisoxazole compounds and their salts are effective in the treatment of various memory dysfunctions characterized by a decreased cholinergic function such as Alzheimer's disease, (see column 2, lines 19-25). Clearly, it would have been obvious to one having ordinary skill in the art to employ these benzisoxazole compounds for disorders related to memory dysfunctions where there is a decrease in the cholinergic function, as taught by O'Malley et al.

Double Patenting

19. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

20. Claims 1-21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 5,538,984. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant invention and U.S. Patent No. 5,538,984 are directed to the improving of a cognitive disorder for the improvement in memory or even treating Alzheimer's disease with the administration of acetylcholinesterase inhibitors of formula (I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

DWAYNE C. JONES
PRIMARY EXAMINER

Tech. Ctr. 1614
April 3, 2002